[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Pre-clinical Evaluation and Commercial Development of Human Therapeutics for Liver Cancer and Ovarian Cancer within the scope of the Licensed Patent Rights

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive evaluation option license to practice the inventions covered under the scope of the following patents and patent applications:

- United States Patent No. 8,207,142 issued Jun 26, 2012 entitled “Inhibitor of DNA Methylation” (HHS Ref. No. E-081-2001/2-US-06);
- EP Patent No. 1418949 issued June 19, 2013, entitled “Inhibitor of DNA Methylation” (HHS Ref. No. E-081-2001/2-EP-02) and validated in Great Britain, Germany and France;
- Australia Patent No. 2002322805 issued February 21, 2008 entitled “Inhibitor of DNA Methylation” (HHS Ref. No. E-081-2001/2-AU-03);
- Australia Patent No. 2008200601 issued November 25, 2010 entitled “Inhibitor of DNA Methylation” (HHS Ref. No. E-081-2001/2-AU-07);
- Canada Patent No. 2,454,147 issued May 21, 2013 entitled “Inhibitor of DNA Methylation” (HHS Ref. No. E-081-2001/2-CA-04);
- Japan Patent Application No. 2003-517229 filed July 30, 2002 entitled “Inhibitor of DNA Methylation” (HHS Ref. No. E-081-2001/2-JP-05); and

- Japan Patent No. 5416660issued November 22, 2013 entitled “Inhibitor of DNA Methylation” (HHS Ref. No. E-081-2001/2-JP-08)

to Metheor Therapeutics, Corporation (“METHEOR”) a US based company located in Shoreline, WA, USA. The patent rights in this invention have been assigned to the government of the United States of America.

The prospective exclusive evaluation option license territory may be worldwide and the field of use may be limited to the pre-clinical evaluation and commercial development of human therapeutics for liver cancer and ovarian cancer within the scope of the Licensed Patent Rights. Upon expiration or termination of the exclusive evaluation option license, METHEOR will have the right to execute a start-up exclusive patent commercialization license which will supersede and replace the exclusive evaluation option license with no broader field of use and territory than granted in the exclusive evaluation option license.

DATE: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [Insert Date 15 Days From Date Of Publication Of Notice In The FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive evaluation option license should be directed to: Sabarni K. Chatterjee, Ph.D.,M.B.A. Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard,

Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5587; Facsimile: (301) 402-0220; E-mail: chatterjeesa@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

The present inventions relate to a potent inhibitor of DNA methylation (Zebularine) that can specifically reactivate silenced tumor suppressor genes. This agent can be used to inhibit methylation and thereby combat certain cancers that have been linked to hypermethylation. This agent has also been shown in initial animal testing to be active orally and is more stable than some other agents in this same area of therapy and is a suitable candidate for further pre-clinical and clinical development as an anti-cancer agent to be used as monotherapy and/or as an adjunct to existing anti-cancer therapeutics.

METHEOR has indicated its interest in developing Zebularine as novel epigenetic modifiers and drugs for oncologic indications. Pre-clinical research and clinical development will primarily focus on determining the safety and efficacy of the lead compound for liver and ovarian cancers.

The prospective exclusive evaluation option license is being considered under the small business initiative launched on October 1, 2011and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive evaluation option license, and a subsequent exclusive patent commercialization license, may be granted unless within fifteen (15) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Any additional, properly filed, and complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive evaluation option license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: February 12, 2014.

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Richard U. Rodriguez,
Director,
Division of Technology Development and Transfer,
Office of Technology Transfer,
National Institutes of Health,

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